Dermasol®

Clobetasol Propionate BP

COMPOSITION

Dermasol® 0.05% ointment: Each gm **Dermasol®** ointment contains Clobetasol propionate BP 0.5 mg.

PHARMACOLOGY

Clobetasol propionate is a highly potent topical steroid. It has both local anti-inflammatory and immunosuppressive activity. Clobetasol, as the propionate salt, is only used topically on the skin and its effects are limited to the local anti inflammatory activity. When given systemically it has standard glucocorticoid activity and binds with high affinity to the glucocorticoid receptor. Clobetasol propionate inhibits the adherence of neutrophils and monocyte macrophages; to the capillary endothelial cells of inflammed area. Clobetasol blocks the effect of macrophage migration inhibitory factor and decreases the activation of plasminogen
to plasmin.

INDICATION

Dermasol® is indicated in:

1. Initial control of all forms of hyperacute eczema in all age groups (in children for no longer than a few days)
2. Chronic hyperkeratotic eczema of the hands and feet and patches of chronic lichen simplex
3. Chronic hyperkeratotic psoriasis of any area of the body
4. Severe acute photosensitivity
5. Hypertrophic lichen planus
6. Localized bullous disorders
7. Keloid scarring
8. Pretibial myxoedema
9. Vitiligo
10. Suppression of reaction after cryotherapy

DOSAGE AND ADMINISTRATION

Apply sparingly to the affected area once or twice daily until improvement occurs. As with other highly active topical steroid preparations, therapy should be discontinued when control is achieved. If a longer course is necessary, it is recommended that treatment should not be continued for more than four weeks without the patient's condition being observed. Repeated short courses of **Dermasol®** may be used to control exacerbations.

If continuous steroid treatment is necessary, a less potent preparation should be used. In very resistant lesions, especially where there is hyperkeratosis, the anti-inflammatory effect of **Dermasol®** can be enhanced, if necessary, by occluding the treatment area with polythene film. Only overnight occlusion is usually adequate to bring about a satisfactory response. Thereafter, improvement can usually be maintained by application without occlusion.

CONTRAINDICATION AND PRECAUTION

Clobetasol propionate is contraindicated in:

1. Cutaneous infections such as impetigo, tinea corporis and herpes simplex2. Infestations such as scabies
3. Neonates (Children less than one year old)
4. Acne vulgaris
5. Rosacea
6. Gravitational ulceration

Long term continuous therapy with Clobetasol propionate should be avoided, particularly in infants and children, in whom adrenal suppression occurs readily. If Clobetasol propionate is required for use in children, it is recommended that the treatment should be reviewed on weekly basis. It should be noted that the infants napkin may act as occlusive dressing. The face more than other area of the body, may exhibit atrophic changes after prolonged treatment with potent topical corticosteroids. This must be borne in mind when treating facial conditions which warrants use of Clobetasol propionate and frequent observation of the patient is important.

SIDE EFFECT

Provided the weekly dosage is less than 50g in adults, any pituitary/adrenal suppression is likely to be transient with a rapid return to normal values once the short course of steroid therapy has ceased. The same applies to children given proportionate dosage. Use of occlusive dressings increases the absorption of topical corticosteroids. Prolonged and intensive treatment with a highly active corticosteroid preparation may cause atrophic changes, such as thinning, striae and dilatation of the superficial blood vessels, particularly when occlusive dressings are used or where skin folds are involved.

DRUG INTERACTION

No information is available.

USE IN PREGNANCY AND LACTATION

Clobetasol propionate should be avoided in pregnant women. Mothers using large amounts of the drug should be aware of potential excretion in milk.

USE IN CHILDREN

The safety and effectiveness of the preparation has not been established in children below the age of 12 years.

OVERDOSE

Acute overdose is very unlikely to occur. However, in the case of chronic overdosage or misuse, the features of hypercorticism may appear and in this situation topical steroids should be discontinued.

STORAGE CONDITION

Store below 30°C. Do not freeze. Keep out of children's reach.

HOW SUPPLIED

Dermasol® 0.05% ointment: Tube containing 5 gm / 10 gm / 20 gm / 30 gm ointment.

SQUARE